ERIKA LIETZAN

William H. Pittman Professor of Law
Timothy J. Heinsz Professor of Law
University of Missouri School of Law

PUBLICATIONS

Academic Law Reviews and Peer-Reviewed Journals

- *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 FORDHAM INTEL. PROP., MEDIA & ENT. L. J. __ (2023) (forthcoming) (with Kristina Acri)
- *The Case of the Missing Device Patents, or: Why Device Patents Matter*, 33 FORDHAM INTEL. PROP., MEDIA & ENT. L. J. __ (2023) (forthcoming) (with Kristina Acri and Evan Weidner)
- *Ignoring Drug Trademarks*, 56 WAKE FOREST L. REV. 945 (2021)
- *Lièvre ou tortue? Les accès anticipés au médicament à l'épreuve du dilemme entre précaution et "droit à l'espoir" des patients*, REVUE DE DROIT SANITAIRE ET SOCIAL 289 (Mars - Avril 2021) (with Isabelle Moine-Dupuis)
- *Distorted Drug Patents*, 95 WASH. L. REV. 1317 (2020) (with Kristina Acri)
- *The "Evergreening" Metaphor in Intellectual Property Scholarship*, 53 AKRON L. REV. 805 (2020)
- *Vers une adaptation de la propriété intellectualle à des stratégies de recherche et de développement: perspectives américaines: Réflexion sur le paradoxe de l'innovation en matière de médicaments*, 54 LE DROIT DES AFFAIRES PHARMACEUTIQUES 71 & 79 (2020)
- *Early Access to Unapproved Medicines in the United States and France*, 19 YALE J. HEALTH POL'Y, LAW, & ETHICS 1 (2020) (with Isabelle Moine-Dupuis)
- *A Special Exception for CBD in Foods and Supplements*, 25 DRUG DISC. TODAY 467 (2019) (with Patricia Zettler)
- *Access Before Evidence and the Cost of FDA's New Drug Authority*, 53 U. RICH. L. REV. 1243 (2019)
- *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 101 (2019) (with Sean O'Connor)
- *The Innovation Paradox: Pharmaceutical Marketing Exclusivity and Incentives for Drug Development*, J. PHARM. HEALTH SERV. RES. 1 (2019) (with Kristina Acri)
- *Paper Promises for Drug Innovation*, 25 GEO. MASON L. REV. 168 (2018)
- *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018)

- *The Drug Innovation Paradox*, 83 MO. L. REV. 39 (2018)
- *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. ONLINE 19
- *The Uncharted Waters of Competition and Innovation in Biological Medicines*, 44 FLA. ST. L. REV. 883 (2017)
- *The Law of 180-Day Exclusivity*, 71 FOOD & DRUG L. J. 327 (2016) (with Julia Post)
- *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. R. 91 (2016)
- *Biosimilar Monoclonal Antibodies: The Scientific Basis for Extrapolation*, 15 EXPERT OPIN. BIOL. THER. 1633 (2015) (with Huub Schellekens, Jaap Venema, and Freddy Faccin)
- *A New Framework for Assessing Clinical Data Transparency Initiative*s, 18 MARQUETTE INTELL. PROP. L. REV. 33 (2014)

Written while in private practice (selected):

- *Thoughts on Preemption in the Wake of the Levine Decision*, 13 J. HEALTH CARE L. & POL'Y 226 (2010) (with Sarah Pitlyk)
- *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L. J. 671 (2010) (with Krista Carver and Jeff Elikan)
- *A New History and Discussion of 180-Day Exclusivity*, 64 FOOD & DRUG L. J. 335 (2009) (with David Korn and Shaw Scott)
- *Current Regulatory and Legal Considerations for Follow-On Biologics*, 84 CLIN. PHARM. & THER. 633 (2008) (with Richard Kingham)
- *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L. J. 49 (2007) (with David Korn)
- *Advisory Committees at FDA: The Hinchey Amendment and "Conflict of Interest" Waivers*, 39 J. OF HEALTH LAW 415 (Fall 2006)
- *2004 Update: 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L. J. 459 (2004)
- *A Brief History of 180-Day Exclusivity under the Hatch-Waxman Amendments*, 59 FOOD & DRUG L. J. 287 (2004)
- *Disgorgement for Violation of the Good Manufacturing Practice Requirement of the Federal Food, Drug, and Cosmetic Act*, 58 FOOD & DRUG L. J. 149 (2003) (with Elizabeth Walsh)
- *An Overview of Canada's Personal Information Protection and Documentation Act for Pharmaceutical and Device Manufacturers*, 57 FOOD & DRUG L. J. 205 (2002) (with John Fuson)

- *Outpatient Civil Commitment in North Carolina: Constitutional and Policy Concerns*, 58 LAW & CONTEMP. PROBS. 251 (Spring 1995)

Books and Book Chapters

- HUTT, MERRILL, GROSSMAN, CORTEZ, LIETZAN, AND ZETTLER'S FOOD AND DRUG LAW (5th ed., 2022) (chapters 6 and 8)
- *Medicines*, in CHEMICALS AND THE LAW (Abelkop et al., eds.) (Edward Elgar Publishing Ltd., 2022, forthcoming) (with Patricia Zettler)
- *Introduction to Medical Products Law*, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2021) (with Patricia Zettler and Aurélie Mahalatchimy)
- *Regulating Medical Devices in the United States*, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2021) (with Patricia Zettler)
- *Regulating Medicines in the United States*, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2021) (with Patricia Zettler)

Written while in private practice:

- *FDA Regulation of Biosimilars*, in FDA IN THE 21ST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES (Lynch & Cohen, eds.) (Columbia University Press: 2015) (with Henry Grabowski)
- *Federal Regulation of Clinical Research*, in MEDICAL BIOTECHNOLOGY: PREMARKET AND POSTMARKET REGULATION (ABA, 2015) (with Afia Asamoah)
- MEDICAL BIOTECHNOLOGY: PREMARKET AND POSTMARKET REGULATION (editor) (ABA, 2015)
- *Biosimilars*, in FOOD AND DRUG LAW AND REGULATION, 3d Ed. (FDLI, 2015) (with Emily Alexander and Laura Sim)
- *Biosimilar Law and Regulation: An Essential Guide*, FDLI Monograph Series (Vol. 2, Number 5) (2011)
- BIOTECHNOLOGY AND THE LAW (editor) (ABA, 2007)
- *The Importance of the Court Decision in Pearson v. Shalala to the Marketing of Food and Dietary Supplements in the United States*, in REGULATION OF FUNCTIONAL FOODS AND NUTRACEUTICALS: A GLOBAL PERSPECTIVE (Blackwell Press & Institute of Food Technologists Press, 2004) (with Peter Hutt and Elizabeth Walsh)

Other Publications

- *How Colombia's Biosimilar Regulation Departs from International Norms*, 41 PAN AMERICAN J. PUB. HEALTH 1 (2017) (letter to editor)

- *The innovation paradox: why complex drug research is not being rewarded*, LIFE SCIENCES INTELLECTUAL PROPERTY REVIEW (July 12, 2017)
- *A Second Look at the CREATES Act: What's Not Being Said*, 17 FED. SOC. REV. 38 (2016)
- *Bill favoring generic drugs will handicap medical innovation*, THE HILL (Nov. 15, 2016) (op ed)

Written while in private practice:

- *Pharmacy Compounding after the DQSA*, 26:4 HEALTH LAWYER (2014) (with Mingham Ji)
- *The Evolving Regulation of Medical Device Clinical Trials in the USA*, JOURNAL OF MEDICAL DEVICE REGULATION (May 2013) (with Emily Alexander)
- *Biosimilar Naming: How Do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars?*, FDLI FOOD & DRUG POLICY FORUM, Vol. 3, Issue 6 (Mar. 2013) (with Laura Sim and Emily Alexander)
- *The U.S. Biosimilar Pathway Nearly Three Years Later*, GXP LIFELINE (Dec. 2012) (with Laura Sim)
- *How Should FDA Use Naming and Labeling to Communicate Information about Biosimilars?*, FDLI FOOD & DRUG POLICY FORUM, Vol. 1, Issue 21 (Nov. 2011) (with Michael Labson and Emily Alexander)
- *Biosimilar regulation: important considerations and global developments*, PLC LIFE SCIENCES HANDBOOK 2011 (Thomson Reuters) (with Peter Bogaert and Laura Sim)
- *Paving the biosimilars pathway: the US and beyond*, SCRIP PHARMA LAW (Dec. 13, 2010) (with Emily Alexander)
- *FDA in Federal Court: The Agency's Ten-Year Record*, FDLI UPDATE (Feb. 2008) (with Megan Quinlan)
- *The Food and Drug Administration Amendments Act of 2007*, 9 BIO-SCIENCE L. REV. 39 (2008) (with Michael Labson and Shaw Scott)
- *Learned Intermediary Doctrine: Required by Law?*, LAW360 (July 17, 2007) (with Michael Imbroscio, Paul Schmidt, Michael Labson, and Miriam Guggenheim)
- *Clinical Trial Registries & Clinical Trial Results Databases*, FDLI UPDATE (Sept. 2005)
- *FDA in Federal Court: Statistics on the Agency's Record in Recent Years*, FDLI UPDATE (July/August 2002) (with Elizabeth Walsh)
- *The Medicine Equity and Drug Safety Act of 2000*, FDLI UPDATE (March/April 2001)

ACADEMIC APPOINTMENTS

University of Missouri School of Law

- William H. Pittman Professor of Law and Timothy J. Heinsz Professor of Law (2020-)
- Associate Professor of Law (with tenure) (2018-2020)
- Associate Professor of Law (2014-2018)

Centre de Recherche Sur le Droit des Marches et des Investissements Internationaux (CREDIMI), Faculté de droit, sciences économique et politique de Dijon, Université de Bourgogne

- Membre associé (2021-)

EDUCATION

Duke Law School (JD with High Honors)

- Order of the Coif
- Senior Editor, LAW & CONTEMPORARY PROBLEMS

University of California - Los Angeles (MA, History)

- Area of focus: intellectual history

University of North Carolina - Chapel Hill (BA, History with Honors)

- Phi Beta Kappa

TALKS AND PRESENTATIONS

Congressional Testimony

- *Antitrust Abuses and the FDA Approval Process*, Statement before the Committee on the Judiciary's Subcommittee on Regulatory Reform, Commercial, and Antitrust Law, U.S. House of Representatives (July 27, 2017)

Academic Programs

- *"Revising Generic Substitution Laws and Combination Medical Products*," Food and Drug Law Journal 2022 Symposium on the Interconnected Regulatory Landscape (November 4, 2022) (moderator of discussion, paper by Amirala Pasha)
- *"Drug Patents and Evidence-Based Policymaking in Patent Law,"* Hudson Institute (April 15, 2022)
- *"The Case for Patents,"* Roundtable Hosted by Classical Liberal Institute, NYU School of Law (May 11, 2021) (invited participant)

- *Direct-to-Consumer Genetic Testing*, Genetics & Medicine: Ethical, Legal & Social Issues (S.J. Quinney College of Law, University of Utah) (Feb. 24, 2021)
- *Intellectual Property and the Constitution*, Hudson Institute Forum for Intellectual Property (Dec. 3, 2020) (roundtable participant)
- *Le marché des médicaments face à l'insatisfaction des besoins des populations: des adaptations d'urgence ou une réforme aux fondements juridiques pérennes?*, Centre de Recherche Sur le Droit des Marches et des Investissements Internationaux (CREDIMI), Universite de Bourgogne, Dijon, France (Nov. 10, 2020)
- *Inventing and 'Reinventing' Under Patent Law*, webinar hosted by Notre Dame Law School's IP & Tech Law Center (Sept. 17, 2020) (panel moderator)
- *Public Health: Regulation, Innovation, and Preparation*, C. Boyden Gray Center for the Study of the Administrative State Research Roundtable (Sept. 17-18, 2020) (invited paper discussant)
- *Intellectual Property Issues in Life Sciences R&D and Commercialization*, WIPO-CPIP Summer School on Intellectual Property (June 12, 2020)
- *Requiring Regulatory Approval of Medical Products: Tradeoffs in a Time of Crisis*, Isolated By The Law, Part 2, An Asynchronous Symposium, Wake Forest University Center for Bioethics, Health, & Society (April 2020)
- *The Assault on Drug Patents*, University of Akron School of Law (Oct. 28, 2019)
- *Ending Exclusivity: The Role of the Orange Book*, Pharmaceutical Innovation, Patent Protection, and Regulatory Exclusivities Symposium, Texas A&M School of Law (Oct. 25, 2019)
- *When Access Precedes Evidence: The Cost of FDA's New Drug Authority*, First Principles for Optimal Regulation Symposium, University of Missouri School of Law (Feb. 8, 2019)
- *Fundamental Rights in U.S. Food and Drug Law*, UFR Droit et Sciences Économique et Politique, l'Université de Bourgogne (Dec. 7, 2018)
- *The Cannabis Legal Landscape Today*, Food and Drug Law Journal 2018 Symposium (Nov. 2, 2018)
- *History and Political Economy of the Hatch-Waxman Amendments*, FDA: Past, Present, and Future, American University Washington College of Law (Oct. 19, 2018)
- *Drug Innovation Out of Order*, Sixth Annual Fall Conference, Center for Protection of Intellectual Property, Antonin Scalia Law School, George Mason University (Oct. 12, 2018)
- *Effective Incentives to Develop New Uses of Established Drugs*, Webcast for the NYS Science & Technology Law Center at Syracuse University College of Law (Mar. 29, 2018)

- *The Political Economy of the Hatch-Waxman Amendments*, Scalia Law School, George Mason University (Mar. 28, 2018)
- *Direct-to-Consumer (DTC) Genetic Testing and Population Health*, Frontiers in Precision Medicine III, University of Utah (Mar. 16, 2018)
- *New Indications for Approved Drugs: Changing the U.S. System*, Clinical Innovation: Fair and Effective Incentives for New Uses of Established Drugs, University College London & Georgetown Law (Feb. 9, 2018)
- *Regulation of Pharmaceuticals in the United States*, UFR Droit et Sciences Économique et Politique, l'Université de Bourgogne (Dec. 10, 2017)
- *Vers une adaptation de la propriété intellectual à des stratégies de recherche et developpement - Perspective americaine*, Le droit des affaires pharmaceutiques, Maison des Sciences de l'Homme, Universite de Bourgogne, Dijon, France (Dec. 8, 2017)
- *Paper Promises for Drug Innovation*, Fifth Annual Fall Conference, Center for Protection of Intellectual Property, Antonin Scalia Law School, George Mason University (Oct. 13, 2017)
- *Sandoz v. Amgen*, 8th Annual Supreme Court IP Review, Chicago-Kent College of Law (Sept. 28, 2017)
- *The Challenges of Encouraging Long Term Innovation*, Fourth Annual CPIP Summer Institute (July 12, 2017)
- *The Drug Innovation Paradox*, Fourth Annual CPIP Summer Institute (July 11, 2017)
- *The New Role of the Administrative State in the Innovation Economy*, Center for the Study of the Administrative State (CSAS) and the Center for the Protection of Intellectual Property (CPIP), Antonin Scalia Law School, George Mason University (May 22, 2017) (discussant)
- Economics Institute for Law Professors, The Henry G. Manne Program on the Law and Economics, Antonin Scalia Law School, George Mason University (May 13-21, 2017) (participant)
- *The Drug Innovation Paradox*, St. Louis University School of Law Faculty Workshop (Nov. 16, 2016)
- *A Framework for Thinking about Biologics Innovation and Competition*, 39th Annual Health Law Professors Conference (June 6, 2016)
- *Set Shifting to the New Biologics System*, Law and Biomedicine Colloquium, S.J. Quinney College of Law at the University of Utah (Feb. 8, 2016)
- *The Myths of Data Exclusivity*, BioIP New Scholars Workshop, Boston University School of Law (May 7, 2015)
- *The Myths of Data Exclusivity*, Washington University School of Law (Mar. 4, 2015)

- *A New Framework for Assessing Clinical Data Transparency Initiatives*, Marquette Law School (Apr. 4, 2014)

Testimony Before Agencies and Judicial/Agency Education Programs

- *The Hatch-Waxman Amendments and Generic Drugs*, The Legal, Economic, and Regulatory Environment of the Pharmaceutical Industry, Mason Judicial Education Program (April 15, 2019)
- *A Global Perspective on Regulatory Standards and Expectations for Biosimilar Biological Medicines*, Presentation to CFDA, Beijing, China (Jun. 18, 2013)
- Approval Pathways and Exclusivity Consequences for Protein Products and Other Biologics, FDA-CDER In-House Training (Dec. 11, 2012)
- Biosimilar Substitution in the EU, Presentation to SFDA, Beijing, China (Nov. 5, 2009)
- Exclusivity Issues Surrounding Therapeutic Biotech-Derived Proteins, FDA-CDER In-House Training (Nov. 29, 2007)
- Exclusivity Issues Surrounding TBPs and Drugs, and, Follow-On Protein Products, FDA-CDER In-House Training (June 14, 2007)
- Post-Approval and Post-Licensure Issues — Biologics vs. Drugs, FDA-CDER In-House Training (Sept. 28, 2006)
- DTC Advertising, the First Amendment & Learned Intermediary Doctrine: A General Introduction to the Legal Framework, Testimony before West Virginia Cost Containment Council (Oct. 20, 2005)

Other Public Speaking Since 2014 (Selected)

- *Catalyst & Health Freedom: Statutory Interpretation in the 11th Circuit (and Beyond)*, Top Cases Panel, Food and Drug Law Institute Annual Meeting (June 15, 2022)
- *Orphan and Rare Disease Development*, Food and Drug Law Institute Annual Conference (May 20, 2021) (panel moderator)
- *The Race for a Coronavirus Vaccine: The Intersection of Science and IP Policy*, MorningsideIP (Sept. 22, 2020)
- *Don't Let a Good Crisis Go to Waste*, Federalist Society COVID-19 & The Law Virtual Conference (June 12, 2020)
- *Eagle v. Azar*, Top Cases Panel, Food and Drug Law Institute Annual Meeting (May 3, 2019)
- *Sandoz v. Amgen*, Top Cases Panel, Food and Drug Law Institute Annual Meeting (May 4, 2018)
- Featured on "This Week in Healthlaw" (Podcast hosted by Professors Terry and Pasquale) (Aug. 1, 2017)

- *Law and Labels: A Regulatory View of Biosimilars*, Wolters Kluwer Clinical Drug Information Webinar (Oct. 30, 2015)
- *Biosimilar Labeling*, DIA Biosimilars 2014 Conference (Sept. 18, 2014)

HONORS AND AWARDS

- American Law Institute (elected 2006)
- Shook Hardy Bacon LLP Excellence in Research Award (for The History and Political Economy of the Hatch-Waxman Amendments) (2019)
- Husch Blackwell Distinguished Faculty Award (teaching award) (2018)
- Best Lawyers in America (FDA Law since 2013, Biotechnology Law since 2007, Washington Biotechnology Lawyer of the Year in 2013)

PROFESSIONAL SERVICE

Administrative Conference of the United States

- Ad Hoc Committee on Regulation of Representatives (2021), Committee on Regulation (2020-), Public Member (2020-)

Food and Drug Law Institute

- Leadership positions since 2004: Chair of the FOOD AND DRUG LAW JOURNAL Editorial Advisory Board (2022), Annual Conference Co-Chair (2021), Annual Conference Planning Committee (2020), Cannabis-Derived Products Committee (2019), Academic Programs Committee (2018), Drug and Biologics Committee (2014-2017), Austern Writing Awards Committee (2013-2014), Board of Directors (2008-2012), and Food and Drug Law Journal Editorial Advisory Board (2004-2008)

Yale Journal of Health Law, Policy, and Ethics

- Advisory Board

Other Peer Review

- Columbia Law Review, Stanford Law Review; New England Journal of Medicine; Jurimetrics; American Journal of Law and Medicine; Food and Drug Law Journal; Generics and Biosimilars Initiative Journal; and Mercatus Center.

NIH/NIAID Grant: R21 AI119633-01, PI: Diane Hoffmann (Microbiota Transplantation: Recommendations for a Regulatory Framework)

- Working group member (2015-2018)

American Bar Association

- Section of Science and Technology: membership and leadership between 2001 and 2017, including Chair of the Biotechnology Committee (five years), Chair of the Life Sciences Division (five years), and Section Council (four years)

- Section of Administrative Law & Regulatory Practice: membership from 2001 to 2017, chair of FDA Committee 2020-

Institute of Medicine

- Consultant to Committee on Strategies for Responsible Sharing of Clinical Trial Data (2014)

American Health Lawyers Association

- Life Science Practice Group, Regulatory Group Co-Chair (2007-2012)

UNIVERSITY SERVICE

University of Missouri

- Campus Faculty Committee on Tenure, Chair (2021-2022)
- Institutional Review Board (2018-)
- Committee on Residency for Tuition Purposes (2016-2018)

University of Missouri School of Law

- Organizer, *Future of Food* Symposium, THE BUSINESS, ENTREPRENEURSHIP, AND TAX LAW REVIEW (March 2022)
- Faculty Advisor, Health Law Society
- Promotion & Tenure Committee (2022-)
- Policy Committee (2019-2021, 2022-)
- Clerkship Committee (2014-) (Chair, 2019-2022)
- Curriculum Committee (2018-2022)
- Law Library Committee (2018-2020)
- Diversity Committee (2017-2018)
- Career Services Committee (2016-2018)
- Dean Search Committee (2016-2017)

COMMUNITY SERVICE

- University of Missouri's University Hospital Wags Therapy Dog Program

PROFESSIONAL AFFILIATIONS

- Food & Drug Law Institute

- American Society of Law, Medicine, and Ethics
- American Association for the History of Medicine
- American Health Lawyers Association
- FDA Alumni Association (honorary member)
- American Intellectual Property Lawyers Association

LEGAL EXPERIENCE

Covington & Burling, LLP, Washington, DC

- Partner (2006-2014), Special Counsel (2005-2006), and Associate (1996-2002)

Pharmaceutical Research and Manufacturers of America, Washington, DC

- Assistant General Counsel (2002-2005)

United States Court of Appeals, 11th Circuit

- Law Clerk for the Honorable Gerald B. Tjoflat (1995-1996)

BAR MEMBERSHIP & ADMISSIONS

- Member of the Missouri, District of Columbia, and North Carolina bars (all inactive)
- Admitted to practice before the U.S. Supreme Court; U.S. Courts of Appeals for the Federal Circuit, D.C. Circuit, Eleventh Circuit, and Tenth Circuit; North Carolina Supreme Court; and United States District Court, District of Columbia